



Champions for Children's Health

401 WYTHE STREET
ALEXANDRIA, VA 22314
P 703-684-1355
F 703-684-1589

6803 WEST 64TH STREET
OVERLAND PARK, KS 66202
P 913-262-1436
F 913-262-1575

May 10, 2012

The Honorable Tom Harkin
Chairman
Committee on Health, Education, Labor
and Pensions
U.S. Senate
Washington, DC 20515

The Honorable Michael Enzi
Ranking Member
Committee on Health, Education, Labor
and Pensions
U.S. Senate
Washington, DC 20515

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairmen Harkin and Upton and Ranking Members Enzi and Waxman:

On behalf of over 220 children's hospitals across the country, you have our full support for the Food and Drug Administration (FDA) user fee legislation as advanced in of your respective committees on April 25, 2012 and May 10, 2012. As an association representing hospitals treating the nation's sickest children, we applaud your dedication to moving bipartisan legislation so the FDA can continue its vital work in ensuring safe and effective life-saving drugs and medical devices will continue to be available to patients in a timely fashion.

We commend the inclusion of provisions intended to address drug shortages, antibiotic resistance and the lack of safety and efficacy information available for pediatric medications. These three areas are essential to improving children's health care and continue to be policy priorities for children's hospitals.

Your efforts to address the escalating public health crisis of drug shortages are especially timely. Our nation depends on children's hospitals to provide care to the most vulnerable pediatric patients, such as children battling cancer. Children's hospitals represent less than 5 percent of all U.S. hospitals, but they treat almost 90 percent of all pediatric cancer. This care is compromised when children's hospitals cannot rely on the nation's pharmaceutical supply chain to produce needed medications. Pediatric oncology has been disproportionately affected by the tripling of drug shortages in recent years, but numerous other critical pediatric drugs and biologics have gone into shortage as well, often with little warning.

We applaud as well the inclusion of provisions enabling hospital pharmacists to alleviate shortages' impact on patient care by providing advance notice when important drugs are expected to be in short supply. This proven approach has enabled the FDA to avoid hundreds of shortages in the last year alone, and we anticipate that this bill will reduce the number of future shortages even further.

Your bills also propose to permanently reauthorize two critically important laws that incentive the study of medications in children – the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA). Together, these laws have reduced the percentage of drugs that must be used off-label—without information on safety or efficacy—in children from 80 percent to 50 percent. While this progress is laudable,

more can be achieved, and your bills additionally make policy improvements further strengthening these laws. Your bills recognize that children have unique needs and require medication specifically developed for them.

Children's hospitals also support the inclusion of language addressing the growing problem of antibiotic resistance. We believe that the incentives in your legislation will aid in our ongoing fight with antibiotic resistant pathogens, such as MSRA, that compromise the health of our immune-deficient pediatric patients.

Finally, please also accept our thanks for your staffs' willingness to work with the Children's Hospital Association and other stakeholders throughout the bipartisan, consensus-focused drafting process. Their efforts and your leadership have resulted in legislation making vastly needed improvements in children's health care. We look forward to its passage into law, and thanks again for your dedication to the health of our nation's children.

Very best regards,

A handwritten signature in dark ink, reading "Mark Wietecha". The signature is fluid and cursive, with the first name "Mark" and last name "Wietecha" clearly distinguishable.

President and CEO
Children's Hospital Association